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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,643	08/21/2003	Adrian Liem	4-32682A	8789

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

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11/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/645,643	LIEM ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

1. This Office Action is responsive to Applicant's response filed June 27, 2007. Claims 21-22 are under examination.

Rejection Maintained

2. The rejection under 35 U.S.C. 103(a) is maintained for claims 21-22 for the reasons set forth on pages 3-5 paragraph 3 of the Final Office Action.

The rejection is reiterated below:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 21-22 are rejected under 35 U.S.C. 103(a) as unpatentable over Clark et al *(Aust. Vet J. 1986, Apr; 63(4):107-10)* in view of Abe et al *(Infection and Immunity, May 1976, p. 1473-1478).*

Claims 21 and 22 are drawn to a method of preventing footrot and liver abscesses in bovines caused by infection with *Fusobacterium necrophorum* bacteria, wherein said method is comprised of:

(a) growing an isolate of *Fusobacterium necrophorum* bacteria, taken from a bovine species, for successive generations in a suitable growth medium for a period of time equal to between 10 hours and 18 hours to form an *Fusobacterium necrophorum* bacteria whole cell culture, with said bacteria culture having a bacterial count population equal to at least 1×10^5 CFU/ml, and wherein said *Fusobacterium necrophorum* whole cell culture contains the growth medium in which said *Fusobacterium necrophorum* is grown:
(b) inactivating said *Fusobacterium necrophorum* culture by contacting said culture with formaldehyde;

(c) forming a vaccine by combining said inactivated *Fusobacterium necrophorum* culture with an amount of diluent; and
(d) administering at least one dosage of said vaccine subcutaneously to a bovine subject with said dosage of about 1 ml to about 2 ml, wherein two dosages of said vaccine are administered.

Clark et al teach that *Fusobacterium necrophorum* is effective in preventing interdigital necrobacillosis (footrot) (see the Abstract). Clark et al teach that vaccine compositions contained whole cultures, of killed cells formulated in a mineral oil adjuvant (page 107-108). Clark et al teach that vaccine compositions comprising culture supernatants provided the most protection against footrot in cattle (see the Abstract and page 109). Clark et al teach that *Fusobacterium necrophorum* can be cultured on suitable medium for a period of time up to 18 hours (page 107). Therefore, the prior art teaches the claim limitation "...successive generations in a suitable growth medium for a period of time equal to between 10 hours and 18 hours to form an *Fusobacterium necrophorum* bacteria whole cell culture, with said bacteria culture." Clark et al teach that a degree of protection against interdigital necrobacillosis was obtained in group 1 and 3 that were given vaccines containing concentrated whole culture (page 109).

Clark et al do not specially teach that the whole cells were inactivated by using formaldehyde nor does Clark et al teach preventing liver abscesses or administering 2 dosages of the vaccine.

Abe et al teach that members of the family *Bacteroidaceae* have been implicated in a variety of infections including liver abscesses (page 1473). Abe et al teach a mouse model in which intraperitoneal injection of bovine strain of *Fusobacterium necrophorum* results in liver abscesses (see the Abstract). Abe et al teach that liver abscesses containing bacteria from the family *Bacteroidaceae* may be associated with 100% morality when undiagnosed (page 1473). Abe et al teach that vaccine compositions comprising formalin killed *Fusobacterium necrophorum* and protected animals from subsequent challenge doses of *Fusobacterium necrophorum* (page 1473). Abe et al teach twenty-four hours post-challenge there was no detectable bacteria in the liver, lung or spleen (page 1475 and figure 3, page 1476). Abe et al teach that extended immunization with formalin killed cells was found to protect mice against F. *necrophorum* infection (see the Abstract).

It would have been *prima facie* obvious at the time the invention was made to use formalin-killed vaccine compositions comprising whole-cell cultures of *Fusobacterium necrophorum* in a method of preventing footrot and liver abscesses in bovine because Clark et al has demonstrated that compositions comprising *F. necrophorum* whole cell cultures are effective in preventing footrot in cattle and Abe et al teach that vaccine compositions comprising formalin killed *Fusobacterium necrophorum* protected animals from *Fusobacterium necrophorum* infections (which included clearance of live abscesses). It would expected barring evidence to the contrary that vaccine compositions comprising formalin killed *F. necrophorum* whole cell cultures would be effective in preventing infections caused by *F. necrophorum*.

Applicant's Arguments

Applicant urges that to establish a *prima facie* case of obviousness, a reference (or combined) must teach or suggest all claim limitations.

Applicant urges that Clark et al teach only three vaccines, none of which contain the growth medium as required by Applicant's claimed invention. Applicant that the vaccine described by Clark et al given to Group 1 does not contain the growth medium at least because this vaccine was prepared by filtering the whole cell culture. Applicant urges that the vaccine describe as given in Group 2 also does not contain the growth medium at least because this vaccine was prepared by sonicating washed concentrated FNBI cells. Applicant urges that the vaccine described as given in group 3 also does not contain the medium at least because this vaccine contained cell-free culture supernatant fluid that has been concentrated 10X using an XM1000 A membrane.

Applicant urges that Abe et al's vaccine also does not contain the growth medium as required by Applicant's claimed invention. Applicant urges that Abe's et al teach immunization with *F. necrophorum* bacteria "grown in PDB broth for 48 h at 37oC, centrifuged, washed three times with saline and formalized.

Applicant urges that because Clark et al and Abe et al when combined do not teach or suggest forming a vaccine that contains the growth medium, the combined references fail to teach or suggest all claim limitations.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed June 27, 2007 have been fully considered but they are not persuasive.

In response to applicant's argument that no *prima facie* case of obviousness has been established, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Clark et al teach whole cell vaccines comprising *Fusobacterium necrophorum* is effective in preventing interdigital necrobacillosis (footrot). Clark et al do not teach the claim limitation "inactivating said *Fusobacterium necrophorum* whole cell culture by contacting said culture with formaldehyde" nor teach preventing liver abscesses. However, Abe et al teach that vaccine compositions comprising formalin killed *Fusobacterium necrophorum* and protected animals from subsequent challenge doses of *Fusobacterium necrophorum*. Thus, one of ordinary skill in the art would be motivated to use vaccines formalin killed *Fusobacterium necrophorum* to protect animals against liver abscesses because Abe et al teach that Abe et al teach that vaccine compositions comprising formalin killed *Fusobacterium necrophorum* and protected animals from subsequent challenge doses of *Fusobacterium*. One of ordinary skill in the art would be motivated

to use vaccines formalin killed *Fusobacterium necrophorum* to protect animals against footrot because Clark et al teach that *Fusobacterium necrophorum* is effective in preventing interdigital necrobacillosis (footrot).

To address Applicant's arguments regarding, Clark et al not disclosing vaccines which comprise growth medium, it should be noted that all of the bacterial cultures used in Clark et al were prepared by growing the F. *necrophorum* FNBI originally isolated from a heifer in modified Eugonbroth (page 107). It should be noted that the Clark et al teach that a degree of protection was obtained in Group 1 which were vaccinated with vaccine compositions comprising whole cell *F. necrophorum* cells. Thus, Clark et al teach the claim limitation "wherein said *Fusobacterium necrophorum* whole cell culture contains the growth medium in which said *Fusobacterium necrophorum* is grown". To address Applicant's arguments regarding Abe et al not teaching the claim limitation "wherein said *Fusobacterium necrophorum* whole cell culture contains the growth medium in which said *Fusobacterium necrophorum* is grown". It should be remembered that it is the combination of references that teach the claimed invention and as stated above Clark et al teach the claimed invention.

In view of all of the above, there is nothing on the record shows that the combination of references do not teach the claimed invention.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanessa L. Ford whose telephone number is (571) 272-0857. The examiner can normally be reached on 9 am- 6 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vanessa L. Ford
Biotechnology Patent Examiner
October 31, 2007

NITA MANSFIELD
PRIMARY EXAMINER